StellarMedical

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Ft. Myers, FL 33907
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K092041

510 (k) SUMMARY
(as required by 807.92(c))

OCT - 2 2009

Submitter of 510(k):

Stellar Medical LLC
10970 S. Cleveland Ave., Suite 403
Fort Myers, FL 33907
USA
Phone: (239) 274-0160
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Contact Person: Spencer Leete

Date of Summary: July 2, 2009

Trade Name: Stellar Fiducial Marker

Common Name: Fiducial Marker

Classification: Class II (21 CFR 892.5050, Product Code IYE)

Classification Name: Medical charged-particle radiation therapy system

Predicate Devices:

Device	510(k) #
Fiducial Markers	K071614

Device Description: The Stellar Fiducial Markers are designed for use in conjunction with conventional radiation therapy methods. The product consists of a solid gold marker, loaded into a standard 17 or 18 gauge brachytherapy needle that has been preplugged with bone wax. The packaged needles are sterilized via ethylene oxide.

Intended Use: The needles are used for interstitial placement of fiducial markers. Once implanted, the fiducial markers serve as localization devices for the purpose of radiation therapy.

Indications for Use: The needles are used for interstitial placement of gold fiducial markers. Once implanted, the gold fiducial markers are used as localization targets for the process in IMRT, and IGRT radiation therapy.

Substantial Equivalence: The Stellar Fiducial Markers are compared to the CIVCO Medical Solutions Fiducial Marker.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Stellar Medical, LLC
% Mr. Benjamin Roedell
Owner
Quality Medical Device Consulting
12738 Buckhorn Dr.
HUDSON FL 34669

OCT - 2 2009

Re: K092041
Trade/Device Name: Stellar Fiducial Marker
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: July 2, 2009
Received: July 15, 2009

Dear Mr. Roedell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092041

Device Name: Stellar Fiducial Marker

Indications for Use: The needles are used for interstitial placement of gold fiducial markers. Once implanted, the gold fiducial markers are used as localization targets for the process in IMRT, and IGRT radiation therapy.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092041